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Written Statement before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information and International Security, United States Senate

Washington, D.C.
May 12, 2005

Malaria

I would like to thank you for convening this important hearing and for inviting me to testify. Thank you for directing attention and putting the spotlight on a very deadly and insidious disease. Malaria affects the health and wealth of nations and individuals. Especially in Africa, it is both a disease of poverty, and a cause of poverty. Malaria is a top priority for USAID in our work in infectious diseases.

I will speak briefly about the problem, burden and challenges malaria, particularly in Africa and outline USAID efforts to battle this disease.

Malaria is an age-old scourge. Today, malaria's heaviest burden falls on young children in Africa. Every 30 seconds, malaria claims a life in Africa - far more than either AIDS or TB. And most malaria victims are children. Worldwide, an estimated 300 to 500 million cases of malaria are contracted every year, resulting in close to 2 million deaths. In Africa - where 90 percent of malaria deaths occur - the disease is the leading killer of children under 5 years of age.

Although overshadowed by the horror of AIDS, malaria has steadily increased the toll it takes. The young die, defenseless. Adults - taken over by bouts of chills and fever - can no longer go to work. Entire families go hungry, as the infected person dies a slow death of anemia, or closing of the vessels of cerebral tissues.

Malaria deaths increased during the 1980s and early 1990s corresponding with treatment failures related to drug resistance. In response, USAID and the global community worked with African countries to change to more effective malaria drugs. USAID also funded research on options for prevention that led to the development of insecticide treated nets as an effective means to get insecticides into peoples homes. ITNs were shown to reduce child deaths from all causes by 17%, and to reduce severe malaria by 45%. As other drugs lose their efficacy along with chloroquine, artemisinin combination therapy drugs are now the most effective drugs available. USAID supported the safety and introduction studies required to roll-out ACTs in Africa.

The U.S. Agency for International Development's programs are making an impact - under five mortality rates are starting to decline in several African countries where malaria interventions have been put to work. In the early 1990s, Malawi was one of the first countries to change treatment policy from using the ineffective Chloroquine to a different drug that was more effective at the time, sulfadoxine pyrimethamine (SP). Infant mortality rates dropped in Malawi in the following years. Insecticide treated nets are now being used by millions of families throughout Africa. Effective drugs will be increasingly available.

Comprehensive Strategy

USAID has in place a comprehensive strategy to battle malaria including, prevention, treatment, and malaria in pregnancy. This strategy also includes special efforts focusing on malaria in complex emergency settings. USAID programs for malaria control are based on a combination of internationally-agreed priority interventions and country-

level needs for achieving the greatest public health impact, most importantly, the reduction of most of the deaths.

These are:

- Prompt and Effective Treatment with an effective anti-malarial drug within 24 hours of onset of fever;
- Prevention of malaria through the use of insecticide - treated mosquito nets (ITNs) targeted to young children and pregnant women, and spraying of homes;
- Provision of Intermittent Preventive Therapy (IPT) for pregnant women as a part of standard ante-natal services.

Each of these interventions is backed by solid evidence of effectiveness under program conditions in reducing the sickness and death from malaria, especially in Africa. The Abuja Targets, set at exceeding 60% coverage for each, were agreed upon by the Heads of State of African countries in 1999, and are the basis for international malaria control efforts in Africa.

Prevention of Malaria

The most effective way to prevent malaria is through the selective use of insecticides that kill the malaria-transmitting mosquito. The international community needs to move aggressively to ensure their widest possible use to protect vulnerable populations from malaria. There are two options for getting insecticides into the homes of those most at risk: indoor residual spraying (IRS) and insecticide treated nets (ITNs). USAID supports the use of both IRS and ITNs. The real challenge is about how to deliver the insecticide to where it can do the most good to protect young children and pregnant women to save as many lives as possible. The choice of which intervention to use should be driven by local conditions and needs.

Indoor Residual Spraying

IRS is the organized, timely spraying of an insecticide on the inside walls of houses. It is designed to interrupt malaria transmission by killing adult female mosquitoes when they enter houses and rest on the walls after feeding, but before they can transmit the infection to another person. There are 12 insecticides approved by the WHO for indoor spraying, one of which is DDT.

USAID supports IRS and we are working with our missions to make sure there are no barriers to supporting if appropriate in that particular setting. USAID is supporting IRS programs in several countries, including Eritrea, Zambia, Mozambique, Kyrgyzstan, Liberia, Angola and Burundi.

There is strong technical consensus that IRS is best suited for areas with sufficient infrastructure to support the necessary logistics - such as in South Africa, or in urban settings when local transmission of malaria is well documented, and in refugee camps. IRS spray programs have been maintained successfully and effectively in some southern African countries, especially where there are large populations exposed to unstable malaria. But these areas do not represent the extremely rural hyper-endemic parts of Africa where most of the deaths occur. The challenge of spraying is greater in many of Africa's remote areas because those hard-to-reach areas must be treated and re-treated often. Both bed nets and spraying are very effective if used correctly. The choice of which intervention to use should be driven by local conditions and feasibility.

ITNs

Soaking bednets with insecticides has been shown extremely effective in protecting people from malaria and can be distributed to the most rural and most vulnerable populations in rural villages where most deaths occur.

By consistently sleeping under an ITN, severe malaria has been shown to decrease sickness by 45%, reduce premature births by 42% and cut all-cause child mortality by 17%-63 %. ITNs can be deployed now in the desperately poor rural areas of countries in Africa where malaria-related mortality is highest, and can be put into the hands of parents who want to protect their children. As a consequence there is a strong international consensus that ITNs, particularly in these rural African settings with a high malaria burden, are the best primary prevention intervention. This is the reason USAID has constructed a prevention program that strongly emphasizes the use of ITNs.

Free Nets To Those Most In Need

USAID promotes targeting free or heavily subsidized ITNs for the most vulnerable (pregnant women and children under five years) and poorest populations - thus ensuring economics are not a barrier to net ownership. This evidence documenting how the use of bednets effectively protects against malaria is based on HHS Centers for Disease Control and Prevention (CDC) field trials supported by USAID.

It is important that this targeted distribution of subsidized ITNs be combined with expanding commercial market distribution to develop systems for ensuring the long-term availability of ITNs. Thus USAID supports expanding commercial market distribution, developing new technologies - especially in the area of long-lasting ITNs, and the growing of ITN production capacity -to ensure adequate supplies of affordable and quality ITNs. There is recent evidence from countries where this combined approach of commercial marketing and targeted subsidies is in play that clearly demonstrates that household coverage with bednets is equally distributed across the socio-economic profile - from the poorest to the wealthiest families.

Tremendous progress has been made in the past several years. For example, ten percent of Nigeria is now covered by an ITN - that is over 10 million people. Malawi net coverage (nationwide) increased from 13% in 2000 to 60% in 2005. ITN coverage also increased from 11% to 43% in Senegal, 9% to 40% in Zambia, 0% to 21% in Ghana.

According to the World Malaria Report the number of ITNs distributed has increased 10-fold during the past 3 years in more than 14 African countries. Subsidized or free-of-charge ITN distribution has proved successful in increasing coverage of the most vulnerable populations. This is often linked to antenatal care and/or child immunization services, or national child immunization campaigns. In all these cases, surveys point to a significant proportion of the nets being used by the primary target groups of children under five and pregnant women. In Tanzania, 53% of children under 5 and 42% of pregnant women were using nets in 2003.

Further, new technologies now provide long-lasting nets and treatments that remove the necessity for retreatment. The increasing availability of long-lasting insecticide treated nets (LLINs) which have an effective lifespan of about four years without the need for retreatment, will remove this requirement altogether.

These technical developments, the product of committed commercial sector engagement with Roll Back Malaria partners, render nets even more cost-effective that before: more affordable, more easily used, and more effective.

Commercial Partnerships to Build Sustainability

ITNs can be delivered through a variety of channels - public sector, NGOs, community groups, and the commercial sector - and can be readily added to existing services, such as antenatal services, or immunization programs. For this reason, ITNs are generally thought to be a very practical and effective means for protecting the large and dispersed populations of highly endemic malaria countries. ITNs have also been demonstrated to be highly deployable in rural Africa.

USAID has developed innovative models for the delivery of highly subsidized or free ITNs in collaboration with national malaria control programs in Ghana, Senegal and Zambia, as well as UNICEF, the United Kingdom Department for International Development (DfID), the International Federation of the Red Cross (IFRC), NGOs and private sector partners such as ExxonMobil. With UNICEF this involves delivery of subsidized ITNs linked to routine immunization; with the Red Cross, ITNs are provided at no cost as part of targeted measles campaigns, and with ExxonMobil, the nets are delivered via a heavily subsidized voucher program through antenatal clinics.

USAID also partners with 13 major commercial firms (representing over 80 percent of the global capacity to produce and distribute ITNs) in a consortium called NetMark. It is an innovative program that is working to share the risks of developing ITN markets, to identify and reduce barriers to effective engagement of the commercial sector, and to create demand, thereby expanding the availability of affordable nets. In five African nations, the program has helped eliminate taxes and tariffs. This effort, joined with that of the many Roll Back Malaria partners to scale-up ITN access and use throughout Africa, can reduce malaria deaths by one million annually. We hope that this successful cooperation with the commercial sector for insecticide-treated netting will serve as a model for future cooperation with the commercial sector in other parts of the world and with other health related products.

USAID is investing in building the capacity of African distributors and their suppliers to distribute and promote ITNs on a national scale. Strategic investments are made to support companies willing to spend its own money to expand through a matching fund scheme, while generic behavior change communication campaigns create demand on a The main barriers to scale up with ITNs have been changing residents' attitudes and behavior, cost of the nets, and limited distribution systems. To overcome these barriers, USAID is supporting targeted distribution of free or highly

subsidized ITNs to children under 5 and pregnant women, extensive social marketing efforts and is working closely with net manufacturers and distributors in many African countries. Such practice was unknown to most rural African populations until the late 1990s.

As a consequence of these efforts we are on a trajectory to provide more than three million ITNs in 2004. USAID anticipates that sales of ITNs in seven target countries in 2005 will at least double and could reach seven million.

Prompt and Effective Treatment

Until recently drugs like chloroquine cured malaria. But drug-resistant strains emerged, lowering the effect of these drugs. As drug resistance increases, the effectiveness of first- and second-line drugs for malaria treatment has been much reduced. Only a limited number of alternative drugs are available and there is little economic incentive for new drug discovery and development, given its high cost and the fact that malaria predominantly affects the world's poorest nations. Furthermore, in many malarious areas, a majority of the population does not have ready access to malaria treatment and those drugs that are available may be of substandard quality.

For a number of years, USAID has been trying to improve access to prompt and effective treatment for malaria. This involves making sure that parents recognize the danger signs of malaria, and bring their child in for treatment immediately. It also means helping to make sure there is an accessable treatment facility with effective drugs available. Because of increasing drug resistance, in many places, traditional first line treatments are no longer effective.

Currently the best treatment on the market for drug-resistant malaria is artemisinin combination therapy (ACT). Based on a traditional Chinese herb, ACTs are extremely effective, yet far more expensive than previous treatments.

USAID is playing a leading role in ACT roll-out. Since 1998, we have backed safety and efficacy testing of artemisinin combination treatment (ACT) in Africa. ACT is a three-day treatment made from the extract of Artemisia annua, or wormwood, a plant that until recently grew only in Vietnam and China. Combining artemisinin with another drug also means that there are two modes of acting, so if 95 percent of the infection is cleared with the artemisinin, the rest is taken care of by the other drug. USAID is working with the Global Fund to Fight AIDS, Tuberculosis and Malaria to make funding available for ACTs and working with 25 countries in Africa to complete the regulatory and public health legwork to roll-out ACTs. USAID also supports the transport, ordering and stocking of ACTs in rural clinics, trains health-care workers and educates parents on the treatment.

Since 2001, 40 countries, including 20 African nations, have switched from old drugs to ACT. An estimated 15 million malaria cases were treated with the drug in 2003, and demand for ACT will rise to 150 million treatments by 2007. But supply of this drug is limited. This will change later this year, when, because of a USAID/WHO partnership with agricultural producers in Africa, African-grown artemisinin hits the market.

In January, USAID helped plant 450 hectares of Artemisia annua in Kenya. And this month, another 450 hectares of the life-saving plant are taking root in Tanzania. Diversifying the location where the plant is grown will allow more drugs to be dispatched around the world faster. Because of the rich soil and warm climate, the African plant may produce much more extract than its Asian sister, treating far more cases. This is expected to lead to an additional 20-40 million pediatric treatments by the end of 2005.

USAID is presently working with 25 Global Fund recipient countries to prepare detailed plans for the introduction of ACT over the next year. Introducing artemisinin to Africa we will not only save millions of lives, but will also provide employment and bring about better opportunities for thousands of farmers.

USAID is strengthening national drug regulatory authorities. The aim is to improve the manufacturing of pharmaceuticals through good manufacturing practices, including drug quality control in national malaria programs. USAID, in addition, is actively working with pharmaceutical companies to upgrade their ACT production capacity in order to increase the pool of companies manufacturing WHO approved ACTs. By 2006 it is expected that worldwide supplies of ACTs will be in line with demand. In the interim, strategic targeting of ACTs will be required to ensure that those countries with high levels of drug resistance have adequate drug supplies.

In addition to making ACTs more widely available, USAID is working in a number of regions to document and address drug resistance. In the Mekong region in Asia, USAID has been instrumental in documenting the extent of the drug-resistant problem in the region as well as studying the factors - such as poor drug use and poor drug quality

that are contributing the emergence and spread of resistance. This three pronged approach in the Mekong has allowed decision-makers to more broadly understand factors that affect community behaviors and to monitor their impact on drug resistance.

Documentation of changes in drug resistance, quality and use will enhance the ability of countries to evaluate their national malaria drug policy and to introduce changes from a more informed perspective. This information is critical for focusing interventions on priority areas in order to preserve the effectiveness of current antimalarial drugs that are safe and affordable. A similar regional effort is underway in the Amazon region of Latin America.

Prevention of Malaria in Pregnancy

Each year, more than 30 million African women become pregnant in malaria-endemic areas and are at risk for Plasmodium falciparum malaria infection during pregnancy. Most women live in areas with year-round malaria transmission, where the infection during pregnancy leads to anemia in the mother and the presence of parasites in the placenta. The resulting impairment of fetal nutrition contributing to low birth weight (LBW) is a leading cause of young infant deaths and development in Africa. HIV infection diminishes even more a pregnant woman's ability to control malaria infections. The prevalence and intensity of malaria infection during pregnancy is higher in women who are HIV-infected. Women with HIV infection are more likely to have symptomatic infections and to have an increased risk for malaria-associated adverse birth outcomes.

WHO has recommended intermittent preventive treatment (IPT) using the antimalarial drug, sulfadoxine-pyrimethamine (SP), as the preferred approach to reduce the adverse consequences of malaria during pregnancy in areas with year-round transmission. Since more than 70% of pregnant women in Africa attend antenatal clinics, Provision of safe and effective antimalarial drugs in treatment doses can be easily linked to antenatal clinic visits. The potential of IPT to attain high levels of program coverage and its benefit in reducing maternal anemia and LBW makes it a preferred strategy in sub-Saharan Africa. In HIV-negative pregnant women, two doses of IPT provide adequate protection, but a minimum of three doses appears to be necessary in HIV positive women.

USAID played a key role in supporting the original studies in Africa that documented the efficacy of IPT in preventing the impact of malaria on both HIV positive and HIV negative pregnant women and their babies. Many countries have already changed their policies to incorporate IPT. Currently, through a coalition of partners, USAID is assisting ministries of health in about 10 African countries to implement IPT and distribute ITNs as part of a package of health interventions at the antenatal clinic level.

Over the last year this technical assistance has contributed significantly to revision of outdated policies in Senegal, Ghana, Rwanda, and Zambia and to increased implementation of revised policies in DRC, Tanzania, and Kenya. Among women attending antenatal services in Tanzania, delivery of intermittent preventive therapy has increased from below 30 percent to over 60 percent.

Expanding Global Network

No one agency can do it all. The international efforts to fight malaria and TB are largely coordinated by global partnerships that include leaders from across the world, health institutions, the World Health Organization (WHO), UNICEF, World Bank, United Nations Development Programme (UNDP), multi-lateral agencies, international, national and local NGOs, and the private sector. USAID is a key partner in this Roll Back Malaria Partnership.

USAID also has developed strong partnerships with many companies, bringing in private dollar side by side to support public programs. USAID is committed to reaching out beyond our traditional partners to find able and creative organizations, particularly those that are faith-based and community-based.

And with so many new partners, the coordination of our efforts becomes even more critical. This is as true among the U.S. government agencies as it is among our international partners, including the new Global Fund. Coordination efforts must occur at two levels: at headquarters and in the countries we are assisting. These actors are fulfilling unique roles - roles only they can perform due to their expertise, positions and responsibilities.

- USAID and HHS work closely to fight malaria, and are coordinating with many others in the Roll Back Malaria Partnership. USAID conducts annual planning meetings with the HHS/CDC and has an Interagency Agreement (IAA) with CDC for specific malaria prevention and control activities. These efforts are well organized and coordinated and benefit from country and leading technical agency input.

- USAID missions work closely with the Global Fund to Fight AIDS, TB and Malaria (GFATM) by leveraging mission funded programs with the substantial funding provided by the GFATM. Through the Global Fund, USAID, HHS and international partners have come together to combine financial, technical, management, and other expertise to reduce the public health impact of malaria. Since 2001, the U.S. government has contributed almost $1.1 billion to the Global Fund, including $459 million for FY 2004. Led by Ambassador Randall L. Tobias, USAID and HHS participate on the Global Fund Board (the U.S. technical review panel of proposed Fund programs), and provide technical assistance in helping the Fund's projects succeed in HIV/AIDS, TB and malaria.
- We are committed through our board participation and technical review panel, as well as in country technical assistance to helping the Global Fund succeed in controlling HIV/AIDS, TB and malaria.
- Research institutions and pharmaceutical companies can develop improved treatments and interventions to help protect us against malaria and its impacts.
- Community- and faith-based organizations and other NGOs extend deeply into many of the most rural areas, reaching societies and cultures to ensure health care services and malaria treatments and interventions get to hard-to-reach populations.
- National governments have especially important roles to play with specific, attainable steps to reducing the impacts of malaria - steps that only they can take. The international donor community, in partnership with developing country partners, can ensure that technical and financial resources are allocated where they will be most effective.

USAID is focusing on the best ways to save the lives of millions from malaria's grip. Too many lives are at stake. Collectively, the international community with the U.S. Government) must gather our will to stop the spread of malaria.